REPRESENTATIVE MIKE KELLY
SIXTEENTH DISTRICT, PENNSYLVANIA

COMMITTEE ON WAYS AND MEANS
RANKING MEMBER, SUBCOMMITTEE ON OVERSIGHT
SUBCOMMITTEE ON HEALTH

Congress of the United States
House of Representatives
Washington, DC 20515

July 16, 2019

Norman E. Sharpless, M.D.
Acting Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Acting Commissioner Sharpless:

I write regarding the steady rise in diabetes diagnoses and the corresponding increase in the cost of insulin to treat the disease. The Centers for Disease Control says more than 30 million Americans are diabetic. Therefore, access to affordable insulin is a public health imperative.

The average annual cost of insulin for a person with type 1 diabetes has reached $5,705, a 600% increase since 2001. Reportedly, this has led to approximately 25% of diabetics rationing their doses because they cannot afford refills of their prescriptions. As insulin prices rise, Americans struggle to find affordable alternatives. This is partly because the regulatory pathway for generic insulin production is currently inhibited for reasons I would like to know and address. Accordingly, I request a detailed response to the following questions:

1. In October 2017, the FDA issued guidance on abbreviated new drug applications (ANDAs) for certain peptide drug products. Insulin was not included in this guidance. I understand that if it were, it could be eligible for generic production. Will you please explain why insulin was not included in the guidance? Please note if there are safety, efficacy, or statutory barriers to its inclusion.

2. If the exclusion of insulin from the 2017 guidance was due to statutory limitations, what legislative action is required to remove such obstacles?

American diabetics, tens of thousands of whom live in Pennsylvania's 16th Congressional District, would benefit from the availability of generic insulin. I will appreciate an expeditious reply to this letter.

Sincerely,

Mike Kelly
Member of Congress

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